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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/624,328

07/22/2003

John McMichael

13024/38627A

6971

4743

7590

04/27/2006

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EXAMINER

JONES, DWAYNE C

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 04/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/624,328	<b>Applicant(s)</b> MCMICHAEL ET AL.	
	<b>Examiner</b> Dwayne C. Jones	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09JAN2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,5,8-18 and 20-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,5,8-18 and 20-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of Claims***

1. Claims 1, 2, 4, 5, 8-18, and 20-24 are pending.
2. Claims 1, 2, 4, 5, 8-18, and 20-24 are rejected.
3. Claims 3, 6, 7, 19, and 25-28 are cancelled as per the amendment of January 9, 2006.

### ***Response to Arguments***

4. Applicant's arguments with respect to claims 1, 2, 4, 5, 8-18, and 20-24 have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Art Unit: 1614

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-7, 11-15, and 19-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frey, II et al. of U.S. Patent Application Publication No. 2003/0072793 A1 in view of Beers, M. H. and Berkow, R., Editors-in-Chief, THE MERCK MANUAL OF DIAGNOSIS AND THERAPY, 17<sup>TH</sup> EDITION, pages 1525-1539 and 1932-1933, 1999.

9. Frey, II et al. teach of the administration of nerve growth factor (NGF) for the treatment of disorders or disease of the CNS, (see paragraphs 50, 51, and, 169). In addition, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The prior art reference of Frey, II et al. teach of using "the preferred neurologic agents" namely growth factors such as nerve growth factor, and others (see paragraph 51). Frey, II et al. also teach the skilled artisan of treating CNS disorders, in particular affective disorders and anxiety

Art Unit: 1614

disorders, (see paragraph 169). Frey, II et al. also teach of various well-known forms of administration, such as sublingual (paragraph No. 121), buccal administration (paragraph No. 123), topical administration (paragraph No. 123), as well parenteral formulations that are known in the art, (see paragraph Nos. 122 and 124-126).

10. Beers, M. H. and Berkow, R., Editors-in-Chief, THE MERCK MANUAL OF DIAGNOSIS AND THERAPY, 17<sup>TH</sup> EDITION disclose that depression (a unipolar) disorder that is falls under the broad definition of class of mood disorders or an affective disorders, (see page 1525). Beers, M. H. and Berkow, R., Editors-in-Chief, also state that individuals with mixed anxiety-depression possess conditions of symptoms that have both anxiety and depression, (see page 1529) and that depressed patients typically are anxious and depressed, (see page 1531). Next, Beers, M. H. and Berkow, R., Editors-in-Chief specifically disclose to the skilled artisan that a patient with the condition of premenstrual syndrome (PMS) is characterized by inter alia anxiety and depression, (see page 1932). Although the prior art, reference of Frey, II et al. is silent to using nerve growth factor for the treatment of the psychological conditions of PMS and anxiety disorders and panic attacks, Frey, II et al. do in fact teach and provide the artisan with the necessary motivation to use nerve growth factor in the treatment of affective disorders and anxiety disorders, (see paragraph 169). Accordingly, one having ordinary skill in the art would have recognized that by treating depression and anxiety, one would also be treating and alleviating the symptoms of related conditions and ailments that have depression and anxiety as symptoms, namely anxiety disorders, PMS and depression associated with menstruation and anxiety associated with panic

Art Unit: 1614

attacks, especially in view of the teaching of Beers, M. H. and Berkow, R., Editors-in-Chief.

11. Moreover, the determination of a specific range of a dosage having the optimum therapeutic index is well with the level of one having ordinary skill in the art, and the artisan would be motivated to determine optimum amounts to get the maximum effect of the drug while minimizing unwanted and/or adverse side effects. Hence, the references make obvious the instantly claimed subject matter.

12. Claims 1-7, 11-15, and 19-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siuciak of U.S. Patent No. 5,599,560 in view of Beers, M. H. and Berkow, R., Editors-in-Chief, THE MERCK MANUAL OF DIAGNOSIS AND THERAPY, 17<sup>TH</sup> EDITION, pages 1525-1539 and 1932-1933, 1999.

13. Siuciak disclose that it is known in the art that nerve growth factor (column 4, lines 16-31) is used for the treatment of depression as well panic disorders, (see column 6, lines 44-65)

14. Beers, M. H. and Berkow, R., Editors-in-Chief, THE MERCK MANUAL OF DIAGNOSIS AND THERAPY, 17<sup>TH</sup> EDITION disclose that depression (a unipolar) disorder that is falls under the broad definition of class of mood disorders or an affective disorders, (see page 1525). Beers, M. H. and Berkow, R., Editors-in-Chief, also state that individuals with mixed anxiety-depression possess conditions of symptoms that have both anxiety and depression, (see page 1529) and that depressed patients typically are anxious and depressed, (see page 1531). Next, Beers, M. H. and Berkow, R., Editors-in-Chief specifically disclose to the skilled artisan that a patient with the

Art Unit: 1614

condition of premenstrual syndrome (PMS) is characterized by inter alia anxiety and depression, (see page 1932).

15. Although the prior art, reference of Siuciak is silent to using nerve growth factor for the treatment of the psychological conditions of PMS and anxiety disorders and panic attacks, Siuciak do in fact teach and provide the artisan with the necessary motivation to use nerve growth factor in the treatment of affective disorders and anxiety disorders, (see column 6, lines 44-65). Accordingly, one having ordinary skill in the art would have recognized that by treating depression and anxiety, one would also be treating and alleviating the symptoms of related conditions and ailments that have depression and anxiety as symptoms, namely anxiety disorders, PMS and depression associated with menstruation and anxiety associated with panic attacks, especially in view of the teaching of Beers, M. H. and Berkow, R., Editors-in-Chief.

16. Moreover, the determination of a specific range of a dosage having the optimum therapeutic index is well with the level of one having ordinary skill in the art, and the artisan would be motivated to determine optimum amounts to get the maximum effect of the drug while minimizing unwanted and/or adverse side effects. Hence, the references make obvious the instantly claimed subject matter.

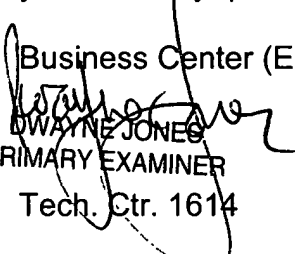
Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (571) 272-0578. The examiner can normally be reached on Mondays, Tuesdays, Wednesdays, and Fridays from 8:30 am to 6:00 pm.

Art Unit: 1614

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, may be reached at (571) 272-0951. The official fax No. for correspondence is (571)-273-8300.

Also, please note that U.S. patents and U.S. patent application publications are no longer supplied with Office actions. Accordingly, the cited U.S. patents and patent application publications are available for download via the Office's PAIR, see <http://pair-direct.uspto.gov>. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site ([www.uspto.gov](http://www.uspto.gov)), from the Office of Public Records and from commercial sources.

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DWAYNE JONES  
PRIMARY EXAMINER  
Tech. Ctr. 1614

April 25, 2006